REMARKS

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

I. Patent Office Interview

Applicant thanks Examiners DeBerry and Allen for the courtesies extended during the December 8, 2010, Patent Office Interview. Applicant's Statement of the Substance of the Interview is provided here, in accordance with MPEP § 713.04. As reflected in the Interview Summary, Applicant proposed claim amendments along the lines presented above. Further, Applicant discussed Sharma's failure to teach or suggest the claimed subject matter.

II. Status of the Claims

Claims 1-33, 35-36, and 38-51 are cancelled without prejudice or disclaimer. (Claims 2-6, 9, 10, 14, 15, 20-33, 35, 36, 38-44, 48 and 49 were cancelled previously.)

Claim 34 is amended to clarify the nature of the recited product, as comprising a first container containing a first pharmaceutical composition comprising recombinant FSH, and a second container containing a second pharmaceutical composition comprising hCG, as described in paragraph [0052], and as discussed during the Patent Office Interview. Claim 34 also is amended to recite specific embodiments with regard to the amounts of FSH, which are supported by, e.g., Figure 1B.

New claims 52, 53, 54, 55, 56 and 57 roughly correspond to, and are supported by, original claims 1, 12, 13, 16, 17 and 18, respectively, and by the specification at, e.g., paragraphs [0045], [0046], [0051] and [0052].

None of the foregoing amendments introduce new matter. The foregoing amendments are made without prejudice or disclaimer, solely to advance prosecution, and not in acquiescence to any rejection. The right to pursue any cancelled subject matter in a continuing application is expressly reserved.

Following entry of these amendments, claims 34, 37 and 52-57 will be pending, of which claim 34 is the sole independent claim. These claims are presented for reconsideration.

III. Withdrawn Rejections

Applicant notes with appreciation the withdrawal of previous rejections over Filicori, Thompson, Menezo and Skrabanja, as set forth at pages 2 and 3 of the Action. Applicant believes that this response overcomes the pending rejections applied to claims 34 and 37, as discussed during the Patent Office Interview and detailed below.

IV. 35 U.S.C. § 112, Second Paragraph, Rejections

The § 112, second paragraph, rejection of claims 34, 37, and 45-47 (page 19 of the Action) is believed to be overcome by the foregoing amendments. Applicant respectfully requests reconsideration and withdrawal.

V. Claim Objections

The objection to claims 50 and 51 (page 19 of the Action) is overcome by the foregoing amendments, which cancel all claims involved in the objection.

VI. Rejections under 35 U.S.C. §§ 102 & 103 Rendered Moot By Claim Cancellation

The following rejections are respectfully traversed but are now rendered ***moot*** in view of the foregoing amendments and the cancellation of the involved claims.

(1) The rejection under 35 U.S.C. § 102(b) of claim 45 over Skrabanja *et al.* U.S. Patent No. 5,929,028 ("Skrabanja") (Action, pages 4-6).

(2) The rejection of claims 1,7, 8, 11-13, 16-19, 50 and 51 under 35 U.S.C. § 102(b) over Franks *et al.* (WO 00/67778) (Action, pages 11-13).

(3) The rejection of claims 1, 11-13, 16-18, 50 and 51 under 35 U.S.C. § 103 over the combination of Filicori *et al.*, "Low-dose human chorionic gonadotropin therapy can improve sensitivity to exogenous follicle-stimulating hormone in patients with secondary amenorrhea," *Fertility and Sterility* 72 (6): 1118-1120 (1999) ("Filicori"); in view of Skrabanja (Action, pages 13-14).

(4) The rejection of claims 1, 11, 13, 16-18, 50 and 51 under 35 U.S.C. § 103 over the combination of Menezo, WO 03/022303 ("Menezo") and Skrabanja (Action, pages 15-18).

VII. Rejections under 35 U.S.C. §§ 102 and 103 Applied to Pending Claims

At pages 6-8, claims 34, 45-47 are rejected under 35 U.S.C. § 102(e) over Sharma *et al.*, U.S. Patent Application Publication No. 2003/0181361 ("Sharma"). At pages 8-10, claim 37 is rejected under 35 U.S.C. § 103 over the combination of Sharma and Skrabanja. Solely to advance prosecution, claims 45-47 are cancelled, and claim 34 is amended as set forth above. Applicant respectfully traverses these rejections in as much as they may be applied to the pending claims.

A. The Claimed Invention

As taught in the specification, Applicant has found that the use of specific amounts of FSH and specific amounts of hCG are particularly effective for treating infertility, such as by showing improved ovulation and pregnancy rates without undesired side effects. Specification, paragraphs [0060] to [0074], and Table 1.

In support of such methods, claim 34 recites a single product comprising (i) a first container containing a first pharmaceutical composition comprising recombinant FSH in an amount selected from the group consisting of 50 IU, 75 IU, and 150 IU and (ii) a second container containing a second pharmaceutical composition comprising recombinant hCG in an amount selected from the group consisting of 1, 2, 3, 4 or 8 μg hCG. Such products are not taught or suggest by the cited references.

B. Sharma Does Not Anticipate

Sharma does not teach or suggest a single product with two containers each comprising specific amounts of specific proteins, let alone the amounts of the proteins recited in the instant claims. As noted in the Office Action, Sharma is directed to extended release formulations of recombinant proteins. Sharma focuses on erythropoietin, but also lists many possible proteins (over 50) that could be formulated in accordance with its technology. Sharma teaches compositions with specific amounts of erythropoietin, but for other proteins discloses only the preparation of compositions with a broad range of ***concentrations***, e.g., 1-2000 μg/ml, and does not provide any teachings on suitable ***amounts*** to be provided in a container, as recited in the instant claims.

Sharma's ***broad*** disclosure of numerous possible proteins would not have led the skilled artisan to a single product comprising ***both*** of the compositions comprising the specific ***proteins*** recited in the claims. Moreover, Sharma's disclosure of a broad ***concentration*** range would not have led the skilled artisan to the ***amounts*** (not concentrations) recited in the claims. Thus, Sharma does not provide any teaching, suggestion or reason to prepare or provide a single product comprising ***both*** (i) an FSH composition and (ii) an hCG composition, as recited in the claims, let alone containers containing such compositions with the recited amounts of each protein.

MPEP § 2131 teaches that a claim to a species is not anticipated by a genus ***unless*** the claimed species can be "***at once envisaged***" from the genus. For example, a very limited genus of 20 compounds disclosed in a Markush group anticipates a single species (*In re Petering*, 301 F.2d 676, 133 USPQ 275 (CCPA 1962)) but a reference disclosing "alkaline chlorine or bromine solution" embraces a large number of species and cannot be said to anticipate claims to "alkali metal hypochlorite" (*In re Meyer*, 599 F.2d 1026, 202 USPQ 175 (CCPA 1979)). Similarly, claims to a process for making aramid fibers using a 98% solution of sulfuric acid were not anticipated by a reference which disclosed using sulfuric acid solution but which did not disclose using a 98% concentrated sulfuric acid solution (*Akzo N.V. v. International Trade Comm'n*, 808 F.2d 1471, 1 USPQ2d 1241 (Fed. Cir. 1986)).

Concerning ranges, the MPEP indicates that prior art which teaches the claimed range or a range touching the claimed range anticipates ***only*** if it discloses the claimed range with "***sufficient specificity***." *Atofina v. Great Lakes Chem.Corp*, 441 F.3d 991, 999, 78 USPQ2d 1417, 1423 (Fed. Cir. 2006). MPEP § 2131.03 (emphasis added).

As noted above, Sharma discloses a large list (over 50) of possible proteins that can be formulated at ***concentrations*** of 1-2000 μg/ml. This provides no information on the ***amount*** of protein that should be provided in a container (as claimed), and certainly provides no "specificity" that could lead the skilled artisan to "at once envisage" the claimed products with (i) a first container containing a first pharmaceutical composition comprising recombinant FSH in an amount selected from the group consisting of 50 IU, 75 IU, and 150

IU and (ii) a second container containing a second pharmaceutical composition comprising recombinant hCG in an amount selected from the group consisting of 1, 2, 3, 4 or 8 μg hCG.

In view of the foregoing, Applicant respectfully urges reconsideration and withdrawal of the §102 rejection based on Sharma.

C. Sharma and Skrabanja Do Not Render Obvious

The rejection of dependent claim 37 under 35 U.S.C. § 103 combines Sharma with Skrabanja. The combination, however, does not remedy the inability of Sharma to teach or suggest the subject matter recited in independent claim 34, from which claim 37 depends. In particular, while Skrabanja was cited for teaching a syringe, Skrabanja does not cure Sharma's inability to teach or suggest the claimed products.

Skrabanja is directed to stabilized liquid gonadotropin formulations. Skrabanja teaches that formulations may be prepared that comprise FSH or hCG or mixtures thereof. Reading Sharma with Skrabanja still does not lead to the present invention, for example, because Skrabanja likewise fails to suggest a container containing a pharmaceutical composition comprising recombinant hCG in an amount selected from the group consisting of 1, 2, 3, 4 or 8 μg hCG, as recited in claim 34. Indeed, Skrabanja discloses only a broad range of suitable amounts of hCG, being "as high as 10,000 IU" and "as low as 15 IU." While this range broadly encompasses the recited amounts, it certainly does not permit the skilled artisan to readily envisage the specific amounts recited in the claims, let alone describe them with any particularity.

As set forth in MPEP § 2144.08, "the fact that a claimed species or subgenus is encompassed by a prior art genus is not sufficient by itself to establish a *prima facie* case of obviousness." The mere possibility that elements of the claim ***can*** be selected from within the broad disclosure of the cited references does not suffice to establish a *prima facie* case of obviousness. Here, where there is no reason to make the asserted selection of (for example) the recited amounts of hCG from the broad range of Skrabanja, an obviousness rejection is not proper.

Reading the references as a whole, the skilled artisan would find no reason to select and combine in a single product both (i) a first container containing a first pharmaceutical composition comprising recombinant FSH in an amount selected from the group consisting of 50 IU, 75 IU, and 150 IU and (ii) a second container containing a second pharmaceutical composition comprising recombinant hCG in an amount selected from the group consisting of 1, 2, 3, 4 or 8 μg hCG. Accordingly, Applicant respectfully urges reconsideration and withdrawal of the obviousness rejection based on Sharma and Skrabanja.

VIII. Obviousness-Type Double Patenting

The provisional obviousness-type double patenting rejections over co-pending applications 11/898,470 and 11/979,265 are maintained at pages 10-11 of the Action. As these applications both are still undergoing active prosecution, Applicant again respectfully defers addressing the rejections on their merits until one or more of the applications are otherwise in condition for allowance.

As noted in MPEP 804, the purpose of a provisional obviousness-type double patenting rejection is to alert the Applicant of the potential problem. The Examiner should continue to make the rejection, as appropriate, unless and until the rejection is the only issue remaining in the first-filed application, or is otherwise overcome on the merits or via a Terminal Disclaimer. Applicant therefore will take the appropriate action, if any is necessary, in due course.

CONCLUSION

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a

check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing or a credit card payment form being unsigned, providing incorrect information resulting in a rejected credit card transaction, or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date December 9, 2010 By _____

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